K004008

p 1/2

DEC 1 3 2001

Exhibit 19
Summary of Safety & Effectiveness

The ***Roamitron*** ™ is designed to perform transcutaneous electrical nerve stimulation (TENS) and as such is a Class II device, having **Regulation Number**: 882.5890 and **Classification Number**: 84GZJ. The **intended use** of this device is for the relief of pain.

This summary is submitted in behalf of:
Dr. Boris Shloznikov
Herbo Medex International, Inc.
7 Tyson Shepway Shepway,
Toronto, Ontario, Canada M2J 4R8
voice phone number-416 492 4614
fax phone number- 416 492 4614

This summary is submitted by:
Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, Connecticut, 06907
voice phone number (203) 329 2700)
fax phone number (203) 329 2345.

This prescription device **is indicated** as an adjunct treatment for the symptomatic relief and management of post-surgical and post-traumatic acute pain using non-invasive nerve stimulation therapy device

The labeling, instructions and user operations are designed to enable the unskilled users to operate this simple device.

Warning
See your physician before using this product.
U S.A. Federal Law restricts this device for sale by or on the order of a licensed practitioner.

Warning
Do not use on the neck or near the Carotid Artery on either side of the neck.

Cautions and Contra-indications

Do not use ***RoamiTron*** ™ if you:
- have a pacemaker,
- have coronary disease,
- have a serious heart rhythm problem,
- have a demand-type cardiac pacemaker,
- are suffering from feverish conditions,
- have an infectious disease,
- have epilepsy,
- have visable skin inflammation.

Do not use ***RoamiTron*** ™:
- near the carotid sinus (neck) region,
- in any treatment to the head (transcerebally),
- whenever pain syndromes are undiagnosed, until etiology is established.

Discontinue treatment with ***RoamiTron*** ™ if:
- skin becomes red,
- skin displays visable damages, or
- skin becomes discolorized,
- Pregnancy occurs.

Consult your physician before changing your prescribed treatment regiment using ***RoamiTron*** ™..

Warnings

The safety of TENS devices for use during pregnancy or birth has not been established.

TENS is not effective for pain of central origin (includes headaches).

Use this device only under the continued supervision of a physician.

The use of this device has no curative value.

This device treats the symptoms and suppresses the sensation of pain that otherwise serve as a protective mechanism.

The user must keep the device out of the reach of children.

Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when TENS stimulation is in use.

Precautions

Caution: Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.

Caution: Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.

Possible Adverse reactions.
Skin irritation and electrode burns are potential adverse reactions.

The ***Roamitron*** ™ is composed of a durable microcontroller (***Roamitron*** ™) and a disposable electrode: ***Roamipad*** ™ . This device can be **described** as a hand held device that uses a microprocessor that is driven by firmware to deliver a calibrated, controlled dose of electrical stimulation to the skin of a patient.

The **scientific concept** on which this device is based, is the principle that pain is treated by sending electrical stimulation through the skin to specific nerve fibers to block or close the gate on signals carrying a pain impulse to the brain. This treatment embodies the gate control theory of pain proposed in 1965 by Dr. Ronald Melzack and Dr. Patrick Wall.

Exhibit 19
Summary of Safety & Effectiveness

This device **functions** by distributing a controlled dose to two electrodes (negative and positive). Since with all TENS devices, the electrodes are placed/moved at different locations on the body, these electrodes also move. These electrodes move by switches the active pair of electrodes among 14 pairs to move the active energy along a roaming pattern over a distance of about 7-inches.

Herbo Medex International, Inc. has determined that the ***Roamitron*** ™ is substantially equivalent to the performance of a an existing medical device: the ***Elpha 2000, Muscle Stimulation*** manufactured by Care Rehab, Inc., 1124 Dominion Court, McLean VA 22102, V-703 448 9644, F- 703 356 2182. The differences between these systems are incidental and not significant. Both devices use a similar technology and principles.

Herbo Medex International, Inc. has determined that the ***Roamipad*** ™ is substantially equivalent to the performance of an existing medical device: the Comfort Stim, K001117, manufactured by: R & D Medical Products, Inc., 20492 Crescent Bay Drive, Suite 106, Lake Forest, CA 92630, V-949 472-9346, F-949 472-9347. The differences between these systems are incidental and not significant. Both devices use a similar technology and principles.

This hydragel used in this electrode assembly has passed the required skin sensitivity, cytotoxicity and biocompatibility testing criteria.

Herbo Medex International, Inc. has determined that *this device* is substantially equivalent to the predicate device and has these similar technological characteristics:

both devices use micro-processors and firmware having digital/analog control of signals,
both devices generate TENS treatment signals having controlled energy levels, duration and waveforms,
both use hydra-gel electrodes.

A series of factory tests are conducted to verify the intended signals are accurate and can maintain a calibrated dose over its useful life. The ***Roamitron*** ™ has benefited from design, development, testing and production procedures that conform to Quality Systems.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. ***Herbo Medex International, Inc.*** continues to search all appropriate sources for information relating to safety and effectiveness and maintains an *in-house* reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

CERTIFICATION:
I hereby certify this **Summary of Safety and Effectiveness** applies for the above indicated device.

Dr. Boris Shloznikov
President
Herbo Medex International, Inc.
7 Tyson Shepway Shepway,
Toronto, Ontario, Canada M2J 4R8
Voice 416 492 4614
Fax 416 492 4614

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2001

Mr. Richard Keen
Herbo Medex International, Inc.
C/O Compliance Consultants
1151 Hope Street
Stamford, CT 06907

Re: K004008
Trade/Device Name: Roamitron controller with Roamipad electrode array
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: GZJ
Dated: October 18, 2001
Received: October18, 2001

Dear Mr. Keen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 2

510(K) Number K-004008

Device Name: *Romitron* ™

a transcutaneous electrical nerve stimulation (TENS) device

Indications for Use

This prescription device **is indicated** as an adjunct treatment for the symptomatic relief and management of post-surgical and post-traumatic acute pain using non-invasive nerve stimulation therapy device

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Discontinue treatment with ***RoamiTron*** ™ if:

- skin becomes red,
- skin displays visable damages, or
- skin becomes discolorized,
- Pregnancy occurs,

Consult your physician before changing your prescribed treatment regiment using ***RoamiTron*** ™..

Warnings

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Caution: Effectiveness is highly dependent upon patient selection by a person qualified in the management of pain patients.

Possible Adverse reactions.

Skin irritation and electrode burns are potential adverse reactions.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhean

(Division Sign-Off)

Prescription Use Division of General, Restorative **Over - The - Counter Use** ___XXX_____

(Per 21 CFR 801.109) and Neurological Devices

(Optional Format 1-2-96)

510(k) Number K004008 Sheet 1 of 1